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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 12/05/2001

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/749,791

Applicant(s)

Keiko

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 17, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/749,791.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, drawn to process for detecting a complementary DNA fragment by hybridization, classified in class 435, subclass 6.
 - II. Claims 4-5, drawn to a kit containing a radiation image storage panel, classified in class 430, subclass 495.1+.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of detecting complementary DNA of Group I can be practiced by the radiation image storage panel of Group II or by Southern blot method using a scintillation counter or fluorometer.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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4. During a telephone conversation with Marc Weiner on August 23, 2001, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-3.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-5 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CAR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(I).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-3, the phrase "such as" used in the specification on page 8, line 6, to refer to particular species of the nucleotide derivatives or analogues renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed

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invention. See MPEP § 2173.05(d). In particular, the ordinary usage of the phrase "nucleotide derivatives or analogues" would ordinarily be understood to refer to nucleotides such as those of Ward (cited in the 103 rejection below) who taught 7-deazapurine linkages. However, the specification appears to define "nucleotide derivatives or analogues" to permit simply ordinary DNA fragments to fall within the scope of the phrase. Therefore, in view of the indefiniteness of this phrase, rejections under both 102 and 103 will be made. The 102 rejection will use the definition found in the specification and the 103 rejection will reject the narrow meaning of the phrase "nucleotide derivatives and analogues".

Claim 2 is rejected over the recitation of the phrase, "barrier member". It is not clear what barrier is claimed and what is meant by barrier member. Is it a chemical including DNA fragments or radioactive label or a physical barrier e.g., plastic or glass or paraffin or a metal? The metes and bounds of the claims are vague and indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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9. Claims 1-3 are rejected under 35 U.S.C. 102 (e) over Some et al. (U.S. Patent 6,256,405 B1) (July 3, 2001).

Some et al teach a process for detecting a complementary DNA fragment which comprises the steps of:

a) bringing single-stranded sample DNA fragments having a radioactive label in a liquid phase into contact with a group of DNA, so that the complementary DNA fragments are fixed by hybridization to the area in which the group is fixed (Column 7, lines 18-38);

b) removing unfixed sample DNA fragments from the hybridized DNA (Column 7, lines 38-43).

C) keeping the hybridized DNA in contact with a radiation image storage panel containing a stimuable phosphor in areas corresponding to the areas on which groups of DNAs are hybridized, so that the corresponding areas of the stimuable phosphor sheet can absorb and store radiation energy of the radioactive label coming from the fixed DNA fragments through the openings (Figures 1 and 8 and Column 7, lines 43-50);

d) irradiating the radiation image storage panel with a stimulating light, so that the image storage panel releases a stimulated emission from the area in which the radiation energy is stored (Figures 1 and 8 and Column 7, lines 51-67 and Column 8, lines 24-28);

e) detecting the stimulated emission photoelectrically to obtain a series of electric signals (Figures 1 and 8 and Column 8, lines 1-23 and 29-52);

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f) processing the electric signals to locate the area in which the complementary DNA fragments are fixed (Figure 6 and Column 12, lines 21-67).

Some et al teach a process, in which area on the radiation image storage panel other than the area of stimuable phosphor is covered by a barrier member (Figures 1 and 8).

Some et al teach a process, in which the irradiation image storage panel is irradiated with a stimulating light after it is separated from the DNA microarray (Figures 1 and 8 and Column 7, lines 51-67 and Column 8, lines 24-28).

Some et al further teach a method in which a solid support having at least two defined areas, each area having a group of nucleotide derivatives, specifically DNA fragments which page 8, line 6 of the specification notes are within the definition of "nucleotide derivatives", under conditions such that the DNA fragments in one area differ in sequence from the DNA fragments fixed in another area (column 7, lines 20-24). In particular, Some states "a plurality of DNA fragments containing specific gene information are separated and distributed on a gel support medium (column 7, lines 20-24)", followed by transfer to nitrocellulose (column 7).

Some et al teach a process, which comprises a DNA micro-array having at least two defined areas in each of which a group of nucleic acids are fixed under such condition that a group of nucleic acids fixed in one area differs from a group of nucleic acids fixed in another area. (Column 23, line 50 to Column 27, line 24).

Some et al teach a process wherein a group of nucleotide derivatives are fixed on the microarray (Column 7, lines 18-38).

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Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-3 are rejected under 35 U.S.C. 103 (a) over Some et al. (U.S. Patent 6,256,405 B1) (July 3, 2001) in view of Linsley et al. (U.S. Patent 6,271,002 B1) (August 7, 2001) further in view of Ward et al. (U.S. Patent 4,711,955).

Some et al teach a process for detecting a complementary DNA fragment which comprises the steps of:

a) bringing single-stranded sample DNA fragments having a radioactive label in a liquid phase into contact with a group of DNA, so that the complementary DNA fragments are fixed by hybridization to the area in which the group is fixed (Column 7, lines 18-38);

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b) removing unfixed sample DNA fragments from the hybridized DNA (Column 7, lines 38-43).

C) keeping the hybridized DNA in contact with a radiation image storage panel containing a stimuable phosphor in areas corresponding to the areas on which groups of DNAs are hybridized, so that the corresponding areas of the stimuable phosphor sheet can absorb and store radiation energy of the radioactive label coming from the fixed DNA fragments through the openings (Figures 1 and 8 and Column 7, lines 43-50);

d) irradiating the radiation image storage panel with a stimulating light, so that the image storage panel releases a stimulated emission from the area in which the radiation energy is stored (Figures 1 and 8 and Column 7, lines 51-67 and Column 8, lines 24-28);

e) detecting the stimulated emission photoelectrically to obtain a series of electric signals (Figures 1 and 8 and Column 8, lines 1-23 and 29-52);

f) processing the electric signals to locate the area in which the complementary DNA fragments are fixed (Figure 6 and Column 12, lines 21-67).

Some et al teach a process, in which area on the radiation image storage panel other than the area of stimuable phosphor is covered by a barrier member (Figures 1 and 8).

Some et al teach a process, in which the irradiation image storage panel is irradiated with a stimulating light after it is separated from the hybridized DNA (Figures 1 and 8 and Column 7, lines 51-67 and Column 8, lines 24-28).

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Some et al further teach a method in which a solid support having at least two defined areas, each area having a group of nucleotide derivatives, specifically DNA fragments which page 8, line 6 of the specification notes are within the definition of "nucleotide derivatives", under conditions such that the DNA fragments in one area differ in sequence from the DNA fragments fixed in another area (column 7, lines 20-24). In particular, Some states "a plurality of DNA fragments containing specific gene information are separated and distributed on a gel support medium (column 7, lines 20-24)", followed by transfer to nitrocellulose (column 7).

While Some et al teach the structure required for DNA microarrays, meeting that limitation, Some et al do not discuss the narrow meaning of microarray as a gridded solid support with bound nucleic acids (which limitation, while currently not in the claims, is shown in figure 1).

Linsley et al teach a process, which comprises a DNA micro-array having at least two defined areas in each of which a group of nucleic acids are fixed under such condition that a group of nucleic acids fixed in one area differs from a group of nucleic acids fixed in another area. (Column 23, line 50 to Column 27, line 24).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute DNA micro-array having at least two defined areas in each of which a group of nucleic acids are fixed under such condition that a group of nucleic acids fixed in one area differs from a group of nucleic acids fixed in another area. of Linsley et al. into the DNA image forming method of Some et al. since Linsley et al. state, "One

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particular useful method of assaying gene expression at the level of transcription employs DNA microarrays (Column 1, lines 53-55).” By employing scientific reasoning, an ordinary artisan would have combined and substituted DNA micro-array having at least two defined areas in each of which a group of nucleic acids are fixed under such condition that a group of nucleic acids fixed in one area differs from a group of nucleic acids fixed in another area of Linsley et al. into the DNA image forming method of Some et al. to improve the process for detecting a complementary DNA fragment. An ordinary practitioner would have been motivated to combine and substitute DNA micro-array having at least two defined areas in each of which a group of nucleic acids are fixed under such condition that a group of nucleic acids fixed in one area differs from a group of nucleic acids fixed in another area of Linsley et al. into the DNA image forming method of Some et al in order to achieve the express advantages , as noted by Linsley et al., of one particular useful method of assaying gene expression at the level of transcription that employs DNA microarrays.

Some et al in view of Linsley et al. do not teach a process wherein a group of nucleotide derivatives and analogues are fixed on the microarray.

Ward et al teach a process of using a group of nucleotide derivatives and analogues (Abstract and Claims 1-21).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method of using a group of nucleotide derivatives and analogues of Ward et al. into the DNA image forming microarray method of

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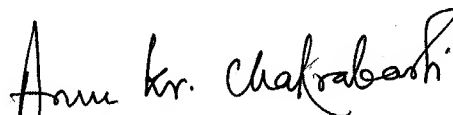
Some et al. in view of Linsley et al. since Ward et al. state, "Application include detection and localization of polynucleotide sequences in chromosomes, fixed cells, tissue sections, and cell extracts. Specific applications include chromosomal karyotyping, clinical diagnosis of nucleic-acid containing etiological agents, e.g., bacteria, viruses, or fungi, and diagnosis of genetic disorders (Abstract, last two sentences)." Ward et al provide further motivation as Ward et al. state, "Moreover, these nucleotide derivatives are chemically stable and can be expected to have functional shelf-lives of several years or more. Finally, these compounds permit the development of safer, more economical, more rapid, and more reproducible research and diagnostic procedures (Column 3, lines 11-17)". By employing scientific reasoning, an ordinary artisan would have combined and substituted the method of using a group of nucleotide derivatives and analogues of Ward et al. into the DNA image forming microarray method of Some et al. in view of Linsley et al. to improve the process for detecting a complementary DNA fragment. An ordinary practitioner would have been motivated to combine and substitute the method of using a group of nucleotide derivatives and analogues of Ward et al. into the DNA image forming microarray method of Some et al. in view of Linsley et al., in order to achieve the express advantages, as noted by Ward et al., of nucleotide derivatives that are chemically stable and can be expected to have functional shelf-lives of several years or more and which permit the development of safer, more economical, more rapid, and more reproducible research and diagnostic procedures and whose application include detection and localization of polynucleotide sequences in chromosomes, fixed cells, tissue sections, and cell extracts and chromosomal

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karyotyping, clinical diagnosis of nucleic-acid containing etiological agents, e.g., bacteria, viruses, or fungi, and diagnosis of genetic disorders.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Arun Chakrabarti,

Patent Examiner,

November 26, 2001